K041305

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Endoscopy

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue 21 CFR §888.3040, Class II
Common and Usual Name:	Bioabsorbable Suture Anchor
Proprietary Name:	Stryker BioZip Suture Anchor System

Predicate Device

Stryker BioZip Suture Anchor System (#K023192), currently marketed by Stryker Endoscopy (San Jose, CA).

Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The line extension of the Stryker BioZip Suture Anchor System is intended for use in providing a means for securing soft tissue to bone using suture. The line extension of the Stryker BioZip Suture Anchor System consists of a Poly L-lactic acid (PLLA) screw-in type anchor pre-threaded with non-absorbable braided polyethylene surgical sutures, and pre-assembled on a disposable inserter.

The line extension of the Stryker BioZip Suture Anchor System will be provided sterile for single-use (ASTM 4169). The device will be sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The device is biocompatible per ISO-10993-1 and G95-1. The line extension of the Stryker BioZip Suture Anchor System is substantially equivalent in material of construction, overall design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The line extension of the Stryker BioZip Suture Anchor System is considered substantially equivalent to the Stryker BioZip Suture Anchor System (#K023192).

Contact:

Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2148

Date: May 7, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2004

Ms. Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K041305
Trade/Device Name: Stryker BioZip Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Fastener, fixation, biodegradable, soft tissue
Regulatory Class: II
Product Code: MAI
Dated: May 7, 2004
Received: May 17, 2004

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041305

Device Name: Stryker BioZip Suture Anchor System

Indications For Use: The Styker BioZip Suture Anchor System is intended foruse in securing soft tissue to bone in such procedures as:

Shoulder:
Rotator cuff repair
Bankart repair
SLAP lesion repair
Acromio-clavicular sepaeration repair
Capsular shift/capsulolabral reconstruction
Biceps tenodesis
Deltoid repair

Knee:
Extra capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Illiotibial band tenosis
Patellar tendon repair

Elbow, Wrist, Hand:
Scapholunate ligament reconstruction
Ulnar collateral ligament reconstruction radial
Collateral ligament reconstruction
Biceps tendon reattachment

Foot & Ankle
Medial instability repair/reconstruction
Lateral instability repair/reconstruction
Achilles tendon repair/reconstruction
Midfoot reconstruction
Hallux valgus reconstruction

Pelvis:
Bladder neck suspension procedures

The Stryker BioZip Suture Anchor System is intended for single-use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041305